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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/625,626 | 07/24/2003 | Steven P. Adams | 14406-003005 | 9041 |

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EXAMINER

COPPINS, JANET L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/625,626 | Applicant(s) ADAMS ET AL. | |
| | Examiner Janet L. Coppins | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7, 10 and 11 is/are allowed.
- 6) ☒ Claim(s) 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-7 and 10-15 are pending in the instant application.

Response to Amendment

1. Receipt is acknowledged of Applicants' Amendment and Response, filed September 28, 2004, which has been reviewed by the Examiner. Accordingly, claim 9 has been cancelled, and claims 1, 11, and 12 have been amended.

Elections/Restrictions

2. The Examiner notes with appreciation the cancellation of non-elected subject matter from the claims.

Response to Arguments

Claim Rejections - 35 USC § 112

3. The Examiner had previously rejected claims 12-15 under 35 USC 112, first paragraph, as not being enabled. Applicants contend on page 9 of the Response that, "The Examiner appears to be under the impression that claim 12 is directed to a method of treating a disease."

Applicants further argue that "The method of claim 12 is **not** directed to a method of treating a disease." Therefore, by Applicants' own admission, the claim has failed to set forth a definable utility, and is therefore not useful. Utility is one of three basic requirements for patentable invention, absent which patent protection is impossible.

Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, and in the previous Office Action, one skilled in the art clearly would not know how to use the claimed invention. The Examiner maintains the rejections to the claims.

4. Claims 12-14 also previously rejected under 35 U.S.C. 112, first paragraph, as being reach-

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through claims. The claims are directed to a method of preventing, inhibiting, or suppressing cell adhesion in a mammal, yet these claims do not meet the requirements for “how to use” under 35 U.S.C. 112, first paragraph, and 35 U.S.C. 101, please see below. As stated in the previous Office Action, the standard of 35 USC 112, first paragraph rejections is that the application itself must inform, rather than direct, others to find out for themselves, please see In re Garnder, 166 USPQ 138. Applicants have still not demonstrated that the specification enables methods of treating the broad number of diseases that they are intending to encompass, which are unrelated. As stated previously, the allegation that the diseases claimed by the Applicants are all treated by inhibiting the binding of ligands to VLA-4 is insufficient support that the claimed compounds have specific efficacy in current available form for treating all of the claimed diseases. Thus, the specification fails to provide sufficient support of the broad use of the compound of the claim 1 for the treatment of all diseases related to “cell adhesion.” Therefore the Examiner maintains the rejections to the claims.

Claim Rejections - 35 USC § 101

5. Claims 12-14 previously rejected under 35 U.S.C. 101 as being reach-through claims, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. As stated previously, the claimed methods of preventing, inhibiting, or suppressing cell adhesion in a mammal do not comply with the utility requirement since no disclosed pharmaceutical use has been recited, i.e. a method of “preventing, inhibiting, or suppressing cell adhesion” is not equivalent to a method of using the product for the treatment of a particular disease, condition, or disorder of real world relevance, please refer to the attached “Reach-Through Claims” article. Again, the Examiner suggests incorporating

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some of the specific diseases that Applicants are enabled for treating in the specification, for example, "A method of preventing, inhibiting, or suppressing cell adhesion in a mammal for treating arthritis, comprising the step of administering...."

Conclusion

6. In conclusion, claims 1-7 and 10-15 are pending in the application, and claims 1-7, 10, and 11 appear to be allowable over the current prior art, while claims 12-15 stand rejected.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
January 7, 2005

for Kamal Saeed
Joseph K. McKane
SPE, Art Unit 1626